

Remarks/Arguments

Claims 1-20 (all claims originally presented) were rejected in the previous Office Action under 35 USC 102(b) and/or 35 USC 103 (a) over a group of references, all of which were cited by applicant.

Claims 6, 8, 10, 14, 15 and 17 were cancelled by the previous amendment.

Claims 1, 2, 9 and 16 and 20 were amended by the previous amendment.

Claims 1, 7, 16, and 20 have been further amended herewith to correct the informalities which Examiner Winakur was kind enough to point out.

Claims 3-5, 11-13 and 18 and 19 are presented in original form.

It is believed that the independent claims 1, 16 and 20 as previously amended and currently corrected place them and the remaining, currently presented dependent claims in condition for allowance. Examiner Winakur's final rejection is therefore respectfully traversed.

Argument

1. Claims 16 & 18 have been rejected under 35 USC 102(e) as anticipated by Presby US Patent No 6,847,496. This rejection is respectfully traversed. Claim 16 is expressly limited to the case where each of the nail, the window plate and the gel have the *same* refractive index. Aside from being directed to transmitted light and hence not directly related to the detection of reflected radiation, the geometry taught by Presby describes a gel or liquid and a window whose index of refraction "substantially match". Attention is specifically directed to Figures 10 and 15 of Presby showing significant refraction due to different refractive indices. Moreover, the exterior plate is specifically described as "translucent". There is no suggestion that the exterior plate, which retains the gel or liquid against the window, must have the same index of refraction as the gel or window as claimed by Applicant. Indeed this is clearly not a requirement of Presby.
2. Claims 1-7, 11 and 13 have been rejected under 35 USC 103 (a) as being unpatentable over Chaiken et al US Patent No. 6,377,828 in view of Simonson et al US Patent No. 5,551,422. This rejection is respectfully traversed. The method of Chaiken involves measuring an analyte in a tissue of a subject. The method comprises contacting the tissue with electromagnetic radiation having a first excitation wavelength, wherein the first excitation wavelength is substantially equal to an absorption wavelength *of a temperature probe within the tissue*. The temperature probe and the analyte are sufficiently proximate to one another that energy deposited into one by absorption of radiation is transferred to the other. The method provides a non-invasive measurement of blood glucose, using hemoglobin as the temperature probe. Applicants claimed method does *not* involve a temperature probe (hemoglobin or any other) proximate to the glucose or other analyte being detected. The Simonson et al patent merely describes various parts of the body which are suitable for spectroscopic analysis, with the fingertip and nail bed being specifically mentioned, and adds nothing to Chaiken et al. Simonson et al specifically requires *plural* light paths and does not address Raman spectroscopy. Furthermore, neither the fingertip nor the nail bed is *the*

same as the sterile matrix. Applicant has set forth in detail in the specification why measurement *in the sterile matrix using Raman spectroscopy*, as specifically claimed by Applicant, is particularly advantageous.

3. Claims 9 and 12 have been rejected under 35 USC 103 (a) over the combination of Simonson et al and Chaiken et al in view of Wach et al US Patent No. 6,370,406. Wach et al was discussed in Applicant's response to the previous office action and is not believed to add any additional relevant disclosure to the teaching of Simonson et al and/or Chaiken et al. The use of a gel on the optic fiber tip "to minimize the influence of the initial boundary" does not alter the fact that Wach et al requires reflection by a reflective fiber surface rather than by the target analyte and specifically teaches the detection of particles of matter present in a volume *bordered by reflective surfaces*. Moreover, its entire focus of Wach et al is on the use of an optic fiber probe (see e.g., col. 13, line 66 to col. 14, line 6). Applicant's invention does not utilize a plurality of reflective surfaces, but rather in contradistinction utilizes reflection by the analyte itself (e.g., glucose).
4. Claim 19 is dependant upon Claim 16. Applicant submits that, as previously discussed, Claim 16 is patentable over the cited reference, and therefore Claim 19 is likewise allowable.
5. Claim 20 has been rejected under 35 USC 103 (a) as being unpatentable over Chaiken et al in view of Simonson et al and Lepper et al, US Patent No. 5,743,262. Applicant does not dispute the general principle that focusing an optical beam in connections with analyte detection is desirable. However Lepper et al adds nothing to Chaiken et al or Simonson et al. Lepper et al does not address Raman Spectroscopy and specifically teaches use of a *broad band* light source, and transmission "*through a fleshy medium*" (italics added). In contrast, Applicant utilizes light of a *fixed* wave length, and Raman spectroscopy of radiation which is *reflected* by the target analyte.

Claim 1, as currently presented, is narrowly focused on the details of the optical



source utilized to generate the radiation reflected by a target analyte present in the sterile matrix under the nail. In addition, the emitted radiation being analyzed is limited to the Stokes Raman. As is apparent from the specification these limitations provide critical and unobvious advantages compared to the prior art analytical techniques described in the references. A critical point applicable to all the references (both 102 and 103), is that with the sole exception of Wach et. al they deal with one or more types of *absorption* spectroscopy and usually require transmission of radiation *through* the part of the body being analyzed. Raman spectroscopy uses reflected radiation and does not, and indeed cannot, be used to detect analytes by passing radiation through a sample.

Applicant does not claim to have been the first inventor to suggest non-invasive spectroscopy for detecting analytes such as glucose inside the human body. Rather Applicant has specifically discovered the unexpected advantages of using a CW, fixed wavelength laser emitting within a specific wavelength range and collecting Stokes Raman optical radiation emitted by an analyte present in the sterile matrix under the nail. None of the cited references, either singly or in combination, teach or suggest this specific analytical technique. It is suggested that Examiner Winakur has utilized Applicant's teaching to select and combine isolated teaching from each of the cited references in an effort to find Applicant's specifically claimed invention, notwithstanding the lack of any basis for such combination.

It is therefore requested that the Examiner reconsider his rejection and pass the currently presented claims to allowance.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Herbert G. Burkard".

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Herbert Burkard

Name

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19 / JAN / 2007

Date

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SN 10/723,042 Filed: 11/26/2003

Title: Optical in-vivo Probe of Analyte Concentration within the Sterile Matrix under the Human Nail

Enclosed are the following documents:

1. Postcard for Return Receipt
2. Express Mail Certificate (1p)
3. Form SB 21 (1 p)
4. Response to Office Action (8pp)